

## PROPERTIES OF THE COMPOSITE

### Adhesion Testing

A qualitative test has been designed to determine whether the composite sticks to tooth structure. A thermal cycling machine was designed to cycle test specimens between two baths. One bath is maintained at 5° C. and the other at 55° C. The temperature range repre-

(c) In most cases the composite was not discontinuous with existing anatomic form (rated A) nor was sufficient restorative missing so as to expose dentin (rated B).

(d) In almost every case there was no visible evidence of a crevice along the margin into which the explorer could penetrate (rated A).

(e) No evidence of caries was observed (rated A).

TABLE B

STATUS OF RESTORATIVE BY INDIVIDUAL TEETH

	Present	Missing	Color Match		Dis-color-ation		Ana-tomical Form		Mar-ginal Adap-tation		Caries A	Total # Teeth Examined
			A	B	A	B	A	B	A	B		
Base Line	90	0	52	38	89	1	89	1	90	0	90	90
6 Months	66	4	27	39	66	0	66	0	65	1	66	70
12 Months	61	4	40	21	56	5	60	1	60	1	61	65

sents the possible extremes found in the mouth e.g. drinking a cold beverage or a hot beverage. Each cycle consists of 10 seconds in cold water, 5 seconds in air and 10 seconds in hot water. A dye is placed in each bath to detect leakage under the restoration.

The specimen preparation requires that the cementum area of the test tooth be cleaned, acid etched, primed and coated with the composite. The tooth is subjected to 1500 cycles on the thermal cycling machine. At the end of the test, the restorative material is knocked off the tooth and the surface under the restorative is examined for dye penetration.

A comparison between cementum areas coated with another composite and with the composite of this invention revealed that cementum areas coated with the other composite lost their restorations after 500 cycles. The cementum areas coated with the composite of this invention did not show any evidence of dye penetration under the restoration when the composite restoration was removed at the end of 1500 cycles. It may be concluded that the composite adheres to the cementum. In a clinical study it was observed that a high percentage of cervical erosion lesions treated in the manner described in this invention were successfully restored.

### Clinical Data

The results are summarized in the Table B entitled "Status of Restorative by Individual Teeth". The evaluations were made using the criteria of the United States Public Health Service. At the base line examination 100 percent of the restorations examined were present, at 6 months, 94.2 percent of the restorations examined were present and at 12 months, 93.8 percent of the restorations were present. The above data indicates that when deep cervical erosion lesions are restored with the composite of the invention, the retention rate is very high.

The composite of the invention was also evaluated for color match, marginal discoloration, anatomical form, marginal adaptation and caries. The results indicated the following:

- In most cases the restoration matched the tooth structure (rated A) or the color match was not outside the normal range of tooth color (rated B).
- In most cases no discoloration occurred in the margin between the composite and tooth structure (rated A) and if discoloration occurred it did not penetrate along the margin of the restorative in a pulpal direction (rated B).

### Toxicity Testing

Samples of the NPG-GMA monomer, the catalyst powder and the universal liquid were placed into several toxicity test procedures using, in general, the "Recommended Standard Practices for Biological Evaluation of Dental Materials", JADA, 84, 382 (1972). The results of these tests indicate that the polymerized materials were found to be non-toxic by mucous membrane test, implantation test and by the oral systemic toxicity test.

What is claimed is:

1. A dental restoration kit for a dentist to use in restoring a non carious erosion lesion of the cervical region of a tooth, said kit being composed of a particulate solid system, a liquid binder system, an etching solution and a primer, all disposed in separate containers, from each of which containers, a dentist may extract necessary amounts of the materials to produce a dental filling to be made, the quantity of material used to produce the filling will match the color of the tooth in which it is to be placed,

(a) the particulate solid system adapted to be mixed with

- for forming the filling material is composed of
  - 95 to 105 parts of a fine silane treated glass,
  - 0.1 to 2 parts of fine silica,
  - 0.5 to 2.5 parts of benzoyl peroxide, and
  - traces of iron oxide pigment as needed for matching the color of tooth structure; and

(b) the liquid binder system adapted to be mixed with

- for forming the filling material is composed of
  - 45 to 65 parts of bisphenol-A/glycidyl methacrylate prepolymer,
  - 5 to 25 parts of hydroxyethyl methacrylate
  - 15 to 45 parts of ethyleneglycol dimethacrylate,
  - 0.001 to 3 parts of methacrylic acid,
  - 0.03 to 0.2 parts of p-methoxyphenol, and
  - 0.05 to 1 parts of N,N-dihydroxyethyl-p-toluidine.

(c) an etching solution of 25 to 50 percent of phosphoric acid adapted to be applied to the tooth for preparing the surface thereof; and

(d) a primer solution of 2 percent N-phenyl glycine/glycidyl methacrylate condensation product in ethanol adapted to be applied to the tooth for forming a bond therewith by chelating with the calcium